NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED, et al., Plaintiffs, v. MSN LABORATORIES PRIVATE LTD. et al., Defendants.	**Civil Action No. 21-10057 (SRC)** **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court pursuant to this Court's Order, filed September 5, 2025, directing the parties to brief an issue of claim construction on an expedited basis. Plaintiffs Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. (collectively, "Bausch") and Defendants MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc., (collectively, "MSN") have briefed a late-arising claim construction dispute over the meaning of the claim term, "trifluoracetic acid (TFA)." For the reasons that follow, this Court agrees with Plaintiffs that the term has its ordinary meaning, trifluoroacetic acid.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d

800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to

> mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed term

The parties dispute the meaning of the phrase, "trifluoroacetic acid (TFA)," which appears in 10 claims in the patents at issue, the '637, '549, and '346 patents. Claim 1 of the '637 patent is representative:

> 1. A purified peptide comprising the GCC agonist amino acid sequence of SEQ ID NO: 1, wherein the purified peptide has the following characteristics:
>
> a) has a bulk density of not greater than 0.1 g/mL;
> b) contains less than 50 ppm acetamide;
> c) less than 0.25% alpha-Asp-9-plecanatide (RRT 1.33) per total weight of peptide; and
> d) less than 0.05% **trifluoroacetic acid (TFA)** per total weight of peptide.

Plaintiffs propose that the term has its ordinary meaning, which is "trifluoroacetic acid." Defendants propose that the term means: "the total of trifluoroacetic acid in its protonated form and its anionic form, trifluoroacetate." The three patents claim priority to the same provisional application. Both parties have chosen to focus their briefs on the record of the '637 patent, and this Court, in this Opinion, follows suit. Plaintiffs contend that the specifications of the three patents are "substantially the same," and Defendants have not disputed this. (Pls.' Opening Br. at 4.)

Plaintiffs contend that "trifluoroacetic acid" is the ordinary meaning of the claim term at issue.[1] The plain language of the claim includes the phrase, "trifluoroacetic acid." The Federal

[1] Dr. Vargas stated: "trifluoroacetic acid (TFA) is an organic acid with a molecular formula of

Circuit has held:

> It is a "bedrock principle" of patent law that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Innova*, 381 F.3d at 1115; *see also Vitronics*, 90 F.3d at 1582 ("we look to the words of the claims themselves . . . to define the scope of the patented invention"); *Markman*, 52 F.3d at 980 ("The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims.").

Phillips, 415 F.3d at 1312. The claims at issue, in unambiguous language, state a limitation of the level of trifluoroacetic acid. Defendants thus must persuade the Court that there is reason to ignore or override the unambiguous language of the claim. They have not done so.

Defendants contend that their proposed construction is the "conventional meaning for the impurity, rather than a 'special meaning.'" (Defs.' Opening Br. at 1.) The Court will not parse Defendants' language on this point but simply observes that Defendants have offered no basis for this Court to conclude that their proposed construction reflects the plain and ordinary meaning of the term at issue, nor have they argued that the construction is based on any disclaimer. Instead, the Court finds that Defendants have proposed a construction based on lexicography:

> A patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history. The intrinsic evidence must clearly set forth or clearly redefine a claim term so as to put one reasonably skilled in the art on notice that the patentee intended to so redefine the claim term.

Alnylam Pharms., Inc. v. Moderna, Inc., 138 F.4th 1326, 1333 (Fed. Cir. 2025) (citations omitted). Defendants have not asserted that the patent specification or file history clearly states, clearly sets forth, or clearly redefines "trifluoroacetic acid (TFA)" in accordance with their proposed construction. On this basis alone, this Court must find that Defendants' proposed

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CF3COOH." (Vargas Supp. Dec. at ⁋ 11.) Dr. Vargas thus shows by her own words that the ordinary meaning of "trifluoroacetic acid (TFA)" is trifluoroacetic acid.

construction does not meet the requirements of Federal Circuit law.

The Court finds that there is one sentence in the specification that demonstrates that Plaintiffs' construction is correct and that Defendants' is not. It is the last sentence of the following paragraph:

> In some embodiments, the purified peptide is substantially free of contaminants resulted from the peptide preparation process such as organic solvents used in the process, e.g., ammonium, acetonitrile, acetamide, alcohol (e.g., methanol, ethanol, or isopropanol), TFA, ether or other contaminants. In this context "substantially" free of contaminants means that the contaminant content of the peptide at the end of the purification process is preferably less than 0.5%, less than 0.3%, less than 0.25%, less than 0.1%, less than 0.05%, less than 0.04%, less than 0.03%, less than 0.02%, less than 0.01%, less than 0.005%, less than 0.003%, or less than 0.001% of the total weight of the peptide. For example, the purified peptide contains <50 ppm acetamide (e.g., ≤35 ppm or ≤18 ppm), <300 ppm acetonitrile (e.g., <250 ppm), <1000 ppm TFA (e.g., <400 ppm, <300 ppm, <200 ppm, <100 ppm, or <50 ppm), <2000 ppm isopropanol (e.g., <1500 ppm, <1000 ppm, <500 ppm, <400 ppm, <300 ppm, <200 ppm, <100 ppm, <50 ppm, or <20 ppm), and/or <0.25% acetate (e.g., <0.2% or <0.1%). The content of contaminants can be determined by conventional methods such as gas chromatography.

'637 patent, col.25 ll.17-37. This paragraph first states that the focus here is: "the contaminant content of the peptide at the end of the purification process." Id. at ll.23-24. The following sentence states limits for various contaminants, including TFA. The final sentence provides the only guidance in the specification about the method for determining the contaminant content of the peptide at the end of the purification process: one can use conventional methods such as gas chromatography.

Both Plaintiff's expert, Dr. Davies, and Defendant's expert, Dr. Vargas, have agreed that the gas chromatography method always measures trifluoroacetic acid content but does not measure trifluoroacetate content unless, before conducting the gas chromatography, the sample undergoes a derivatization step. Dr. Vargas wrote:

> I am aware of several analytical approaches that have been applied for the quantification of residual TFA in peptides and other biologically-relevant matrices. Gas chromatography (GC) and ion chromatography (IC) have historically been used. It is important to note that in order to detect TFA in certain sample matrices via GC, chemical derivatization of the TFA anion is necessary. For example, the TFA anion can be derivatized to form a new compound, such as the TFA-methyl ester, which is volatile. The volatility of the TFA-methyl ester allows it to be analyzed via gas chromatography.

(Vargas Rebuttal Rpt. at ⁋ 42, Frese 7/15/25 Dec. Ex. 11.) Here, Dr. Vargas relies on the fact that, absent "chemical derivatization of the TFA anion," the TFA anion, which is trifluoroacetate and is not volatile,[2] will not be measured by gas chromatography.

Dr. Davies wrote:

> Dr. Vargas similarly disregards the '637 patent's disclosure that "[t]he content of contaminants"—such as TFA—"can be determined by conventional methods such as gas chromatography." . . . As Dr. Vargas evidently appreciates, *see* Vargas Rebut. Report ¶ 42, a POSA reviewing this disclosure would understand that gas chromatography, without more, run on a purified peptide would measure only the quantity of volatile TFA—and not the amount of nonvolatile trifluoroacetate—present in the purified peptide. This, in my view, would indicate to a POSA that "TFA," as it is used in the '637 patent's specification, refers only to trifluoroacetic acid—not trifluoroacetic acid and trifluoroacetate. Dr. Vargas's opinion, which presumes a POSA would perform derivatization before running "gas chromatography" to quantify TFA content, *see id*., ignores that derivatization is only performed for certain matrixes and that such derivatization was not suggested in the '637 patent's specification.

(Davies Reply Rpt. at ⁋ 18, Frese 7/15/25 Dec. Ex. 12.)

The Court now makes findings of fact that are subsidiary to the claim construction. The Supreme Court has held:

> In some cases, however, the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art

[2] Dr. Vargas stated: "The trifluoroacetate ion and salts thereof are not volatile; they have low vapor pressures and do not readily enter the gas phase." (Vargas Rebuttal Rpt. at ⁋ 40, Frese Dec. Ex. 11.)

> during the relevant time period. *See, e.g.*, *Seymour v. Osborne*, 78 U.S. 516, 11 Wall. 516, 546, 20 L. Ed. 33 (1871) (a patent may be "so interspersed with technical terms and terms of art that the testimony of scientific witnesses is indispensable to a correct understanding of its meaning"). In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the "evidentiary underpinnings" of claim construction that we discussed in *Markman*, and this subsidiary factfinding must be reviewed for clear error on appeal.
> . . .
> The district judge, after deciding the factual dispute, will then interpret the patent claim in light of the facts as he has found them. This ultimate interpretation is a legal conclusion.

Teva Pharms. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 331-32 (2015). In the instant case, there are certain undisputed facts which are the underpinnings of the claim construction. Based on the points of agreement between the reports of both Plaintiffs' and Defendants' experts, this Court finds the following undisputed facts:

1. Trifluoroacetic acid is a volatile substance; trifluoroacetate is not a volatile substance.

2. The gas chromatography technique measures/quantifies only volatile substances.

3. Absent a derivatization step to chemically modify trifluoroacetate, gas chromatography will not measure or quantify trifluoroacetate. Gas chromatography will measure/quantify trifluoroacetic acid.

As already discussed, the specification states: "The content of contaminants can be determined by conventional methods such as gas chromatography." '637 patent, col.25 ll.35-37. Since the specification states that gas chromatography can be used for this purpose, and since the Court has found that gas chromatography by itself does not measure trifluoroacetate, but only trifluoroacetic acid, Plaintiff's construction must be correct. If Defendants' construction was adopted, it would make false the specification statement that the content of contaminants can be determined by gas chromatography. Plaintiffs' construction is consonant with this specification statement.

The Court is not persuaded by Defendants' other arguments. Defendants contend that the specification refers to "TFA" as "a residual salt (i.e., anionic)." (Defs.' Opening Br. at 1.) At the outset, it is the Court's understanding that trifluoroacetate is an anion and is not a salt. Dr. Vargas states: "When deprotonated, the trifluoroacetate anion and salts thereof are not volatile;" this statement shows that the trifluoroacetate anion is different from the "salts thereof" (i.e., the salts which contain the trifluoroacetate anion.) (Vargas Supp. Dec. at ¶ 12.) Thus, the salt, sodium trifluoroacetate, is an example of a salt which contains the trifluoroacetate anion bound to a sodium cation. Defendants appear to be blurring the boundary between an anion and a salt as they advance two alternative propositions: 1) the specification refers to TFA as a residual salt; and 2) the specification refers to TFA as the trifluoroacetate anion. (See Defs.' Opening Br. at 9.)

In support, Defendants point to these two statements in the specification: 1) "In addition, the lyophilized plecanatide product also had a high variability of residual salt levels such as TFA, acetate, and ammonium salts" ('637 patent, col.7 ll.31-32); and 2) "The peptide at the end of the purification or isolation processes of the invention has . . . low levels of residual salts (e.g., <0.1% TFA, 0.08-0.23% acetate, and 0.11-0.17% ammonium)" ('637 patent, col.8 ll.9-18).

At the outset, the Court observes that, while the parties may dispute the meaning of "TFA" in these two statements, they are both very clear that both statements address the subjects of TFA salts, as well as acetate salts and ammonium salts. The statements concern TFA salts, and, therefore, "TFA" is a modifier of "salts." These are not examples of "TFA" used in isolation, but as part of the expression of the concept of TFA salts.

The question to ask here is: what does "TFA" mean as a modifier of "salts" in these two

statements? When framed in this way, it is immediately apparent that "TFA" does not mean "TFA salt," which would make that phrase, "TFA salt salts." Defendants propose a second interpretation, that "TFA" in these sentences means "trifluoroacetate," making "TFA salts" mean "trifluoracetate salts." While this sounds possible, would it make sense to a POSA? Defendants' brief cites Dr. Vargas' declaration, which does not address the issue of whether a POSA would understand "TFA salts" to mean "trifluoroacetate salts."[3] (Vargas Dec. at ⁋ 27.) The connection to trifluoroacetate appears to come from Defendant's proposition that the salt form of trifluoroacetic acid is trifluoroacetate. (See Defs.' Opening Br. at 9.) As already discussed, Dr. Vargas distinguished the trifluoroacetate anion from a "salt thereof." In short, Defendant's analysis of the two specification statements makes no sense.

Dr. Davies, on the other hand, offers a viable interpretation of the concept of "TFA salts" implicit in the two specification statements. Surprisingly, Defendants include a footnote to Dr. Davies' deposition testimony, which does not support Defendants' position. (Defs.' Opening Br. at 9 FN 25.) In the cited deposition testimony, Defendants questioned Dr. Davies about these two specification quotes, and Dr. Davies testified that a POSA would understand those sentences to refer to the salt form of trifluoroacetic acid. (Frese Dec. Ex. 15 at 164:22-166:3.) Moreover, Dr. Davies went on to state: "If it says 'salts, e.g., TFA,' they would understand that it's a salt derived from trifluoroacetic acid." (Frese Dec. Ex. 15 at 167:1-16.) The Court is persuaded that, as Dr. Davies testified, a POSA would understand "TFA" in the two cited specification statements about residual salts to modify the word "salts" in the same

[3] In fact, in the Vargas Supplemental Declaration, Dr. Vargas emphasizes that "TFA" refers to both a residual solvent and a residual salt. (See Vargas Supp. Dec. at ⁋ 23.) As already stated, Dr. Vargas equates "TFA residual salt" with "trifluoroacetate." Id.

sentence, so that, together, they identify a genus of residual salts derived from trifluoroacetic acid.

Thus, the Court finds that the parties have proposed two possible ways of looking at the two "TFA salts" specification statements. As Dr. Davies explained, "TFA salts" makes sense when "TFA" is understood to be the abbreviation for trifluoroacetic acid. Defendants propose that "TFA salts" makes sense when "TFA" is understood to be the abbreviation for trifluoroacetate. The problem for Defendants is twofold: 1) this is not close to a clear redefinition of "TFA;" and 2) if "TFA" means trifluoroacetate, and "trifluoroacetic acid (TFA)" is understood to mean "TFA acid or anion," the specification statement about the use of gas chromatography to determine the content of contaminants becomes erroneous. Plaintiffs' construction does not create such problems.

Moreover, Defendants support their theory with a discussion of the specification that blurs together two different kinds of analyses. For example, Defendants state:

> Further still, the specification identifies that the content of contaminants such as "TFA" can be measured by "conventional methods," and the purity of the peptides produced in Examples 4, 5 and 8 was measured by HPLC or ultra-performance liquid chromatography ("UPLC"), which is similar to HPLC but more sensitive. As noted in Section III.C, supra, a POSA would have known that such conventional methods for measuring trifluoroacetic acid in peptides determine the total concentration of trifluoroacetic acid and trifluoroacetate. By contrast, there is no conventional method that measures only trifluoroacetic acid in its protonated form.

(Defs.' Opening Br. at 9-10.) In the first quoted sentence above, Defendants recognize the two different analyses: 1) "content of contaminants such as 'TFA';" and 2) purity of the peptides. These are different and distinct, but Defendants appear to blur them together. The first kind of analysis identifies and quantifies the content of contaminants, such as "TFA." The second kind

of analysis measures the purity of the peptide product as a percentage of the total sample. Indeed, the specification teaches that the purity of the peptide may be determined by HPLC, just as Defendants contend; the specification refers to this analysis as "chromatographic purity" or "HPLC purity."

Defendants do not, however, point to any evidence that the patent teaches that the first kind of analysis, content of contaminants, may be done by HPLC. It is through a content of contaminants analysis that one would determine the level of "trifluoroacetic acid (TFA)," as it appears in claim 1(d). In support, Defendants cite first the content of contaminants paragraph in the specification, col.5 ll.26-46, which, as already discussed, states that the content of contaminants may be determined by conventional methods such as GC. Next, Defendants point to the Supplemental Declaration of Dr. Vargas, which states that the TFA measurements in Table XX of the specification were measured by HPLC or a similar method, UPLC. (Frece Dec. Ex. A at ¶ 29.) In support, both Dr. Vargas and Defendants' opening brief point to Examples 4, 5, and 8 in the patent specification, none of which state that the final level of TFA was measured by HPLC. Example 5 does end with this statement: "HPLC purity after precipitation was 98.47%." '637 patent, col.96 ll.30-31. This statement makes no reference to TFA; instead, it refers to a measurement of peptide purity which, as already stated, is a different kind of analysis which the specification teaches may be done by HPLC. The same is true in Example 8, which teaches the use of HPLC to measure, for example, "HPLC percent purity of the linear crude peptide." '637 patent, col.100 l.57. As Plaintiffs' responsive brief points out, the specification does teach the use of HPLC to determine the purity of the peptide itself, but this is different from analyses to determine the content of contaminants.

Lastly, Dr. Vargas points to the NDA that was filed with the FDA when Synergy Pharmaceuticals applied for new drug approval for their plecanatide product. (Frece Dec. Ex. A at ⁋ 29 FN 46; NDA at Frece Dec. Ex. 22.) While the NDA document does indicate that HPLC was used to determine the TFA impurity content of various product samples, this document is not part of the intrinsic record of the patents at issue. (Frece Dec. Ex. 22 at TRUL00012720.) The NDA filed with the FDA by a pharmaceutical company is not intrinsic evidence of the meaning of a claim term in an issued patent. The patent itself does not identify the methods by which the TFA measurements in Table XX were obtained, and Defendants have not persuaded the Court that a POSA, reading the entire patent, including Table XX, would have understood "trifluoroacetic acid (TFA)" to have a special definition which includes trifluoroacetate.

Plaintiffs have proposed that "trifluoroacetic acid (TFA)" has its ordinary meaning of trifluoroacetic acid. The Court finds that Defendants have proposed a construction which relies on a lexicographic meaning of the claim term which, under Federal Circuit law, requires that the "intrinsic evidence must clearly set forth or clearly redefine a claim term so as to put one reasonably skilled in the art on notice that the patentee intended to so redefine the claim term." Alnylam, 138 F.4th at 1333. Defendants have failed to demonstrate that the intrinsic evidence clearly redefines the claim term at issue.[4] The Court concludes that Plaintiffs' construction is correct.

[44] In fairness, Defendants set for themselves a difficult task – persuading that the phrase "trifluoroacetic acid (TFA)" was clearly redefined in the specification using only the last 5 characters in the phrase, relying on being able to demonstrate a clear redefinition of an abbreviation without any redefinition of the thing that was abbreviated. Wouldn't a claim with an element followed by an apparent abbreviation (but with a different meaning), be likely to raise indefiniteness problems?

In conclusion, the Court construes the term at issue as follows. The term "trifluoroacetic acid (TFA)" has its ordinary meaning, which is "trifluoroacetic acid."

SO ORDERED.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: September 26, 2025